Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-11EC]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Ron Otten, at 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Epidemiologic Study of Health Effects Associated With Low Pressure Events in Drinking Water Distribution Systems — New — National Center for Emerging and Zoonotic Infectious Diseases - Office of Infectious Diseases – Centers for Disease Control and Prevention

Background and Brief Description

In the United States (U.S.), drinking water distribution systems are designed to deliver safe, pressurized drinking water to our homes, hospitals, schools and businesses. However, the water distribution infrastructure is 50-100 years old in much of the U.S. and an estimated 240,000 water main breaks occur each year. Failures in the distribution system such as water main breaks, cross-connections, back-flow, and pressure fluctuations can result in potential intrusion of microbes and other contaminants that can cause health effects, including acute gastrointestinal and respiratory illness.

Approximately 200 million cases of acute gastrointestinal illness occur in the U.S. each year, but we lack reliable data to assess how many of these cases are associated with drinking water. Further, data are even more limited on the human health risks associated with exposure to drinking water during and after the occurrence of low pressure events (such as water main breaks) in drinking water distribution systems. A study conducted in Norway from 2003-2004 found that people exposed to low pressure events in the water distribution system had a higher risk for gastrointestinal illness. A similar study is needed in the United States.

The purpose of this data collection is to conduct an epidemiologic study in the U.S. to assess whether individuals exposed to low pressure events in the water distribution system are at an increased risk for acute gastrointestinal or respiratory illness. This study would be, to our knowledge, the first U.S. study to systematically examine the association between low pressure events and acute gastrointestinal and respiratory illnesses. Study findings will inform the Environmental Protection Agency (EPA), CDC, and other drinking water stakeholders of the potential health risks associated with low pressure events in drinking water distribution systems and whether additional measures (e.g., new standards, additional research, or policy development) are needed to reduce the risk

for health effects associated with low pressure events in the drinking water distribution system.

We will conduct a cohort study among households that receive water from five water utilities across the U.S. The water systems will be geographically diverse and will include both chlorinated and chloraminated systems. These water utilities will provide information about low pressure events that occur during the study period using a standardized form (approximately 12 events per utility). Utilities will provide address listings of households in areas exposed to the low pressure event and comparable households in an unexposed area to CDC staff, who will randomly select participants and send them an introductory letter and questionnaire. Consenting household respondents will be asked about symptoms and duration of any recent gastrointestinal or respiratory illness, tap water consumption, and other exposures including international travel, daycare attendance or employment, consumption of under-cooked or unpasteurized food, animal contacts, and recreational water exposures. Study participants may choose between two methods of survey response: a mail-in paper survey and a web-based survey. Participation in this study will be voluntary. No financial compensation will be provided to study participants. The study duration is anticipated to last 24 months. An estimated 5,200 individuals will be contacted and we anticipate 2,080 utility

customers (18 years of age or older) will consent to participate in this study. We will conduct a pilot study (duration 3 months) prior to launching the full epidemiologic study. An estimated 1,000 individuals will be contacted and we anticipate 400 adults (18 years of age or older) will consent to participate in the pilot study. The total estimated annualized hours associated with this study, including the pilot, is expected to be 467.

There are no costs to respondents other than their time.

Estimate of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respon-dents	Number of Responses per Respondent	Average Burden per Respondent (in hours)	Total Burden (in hours)
Full Study:					
Households	Introductory letter	2,600	1	1/60	44
	Web-based questionnaire	624	1	12/60	125
	Paper-based questionnaire	416	1	12/60	84
Utility employees	Household Listing	5	6	15/60	6
	Water sample collection	5	6	1	30
	Low pressure event form	5	6	4	120
Pilot Study Households	Introductory letter	500	1	1/60	8
	Web-based questionnaire	120	1	12/60	24
	Paper-based questionnaire	80	1	12/60	16
Utility employees	Household Listing	1	2	15/60	1
	Water sample collection	1	2	1	2
	Low pressure	1	2	4	8

	event form				
Total (Full & Pilot)					467

DATE: March 19, 2012

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[FR Doc. 2012-7020 Filed 03/22/2012 at 8:45 am; Publication Date: 03/23/2012]